ATTACHMENT 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Lachman Consultant Services Inc.
Attention: Robert W. Pollock
1600 Stewart Avenue
Westbury, NY 11590

MAY 26 1998

Docket No. 97P-0347/CP1

Dear Mr. Pollock:

This is in response to your petition filed on August 15, 1997, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Oxycodone and Acetaminophen Tablets USP, 2.5 mg/325 mg, 7.5 mg/325 mg and 10 mg/325 mg. Subsequently, on December 8, 1997, you withdrew reference to Oxycodone and Acetaminophen Tablets USP, 7.5 mg/325 mg and 10 mg/325 mg. Therefore, this response addresses your proposed product Oxycodone and Acetaminophen Tablets USP, 2.5 mg/325 mg only. The listed drug product to which you refer in your petition is Percocet® (Oxycodone and Acetaminophen Tablets USP) Tablets, 5 mg/325 mg, manufactured by Dupont Merck.

We have reviewed your petition under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act) and have determined that it is approved. This letter represents the Agency's determination that an ANDA may be submitted for the above-referenced drug product.

Your request involves a change in strength of the oxycodone hydrochloride component from that of the listed drug product (i.e., from Oxycodone and Acetaminophen Tablets USP, 5 mg/325 mg to Oxycodone and Acetaminophen Tablets USP, 2.5 mg/325 mg) The change you request is the type of change that is authorized under the Act.

Under Section 505(j)(2)(C)(i) of the Act, the Agency must approve a petition seeking a strength which differs from the strength of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing strength.

The Agency finds that the change in strength for the specific proposed drug product does not pose questions of safety or effectiveness because the uses, and route of administration of the proposed drug product are the same as that of the listed drug

product. The Agency concludes, therefore, that investigations are not necessary in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug product can be expected to have the same therapeutic effect as the listed reference drug product.

It is recognized that when an ANDA is submitted, the proposed labeling should be revised to reflect the maximum number of tablets per day. This is to ensure that the recommendations for the acetaminophen component will not exceed the maximum total daily dose for adults of 4000 mg established by the Agency for its safe and effective range. Please refer to the Tentative Final Monograph for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use. 53 Fed. Reg. 46204, 46236 (November 16, 1988).

The approval of this petition to allow an ANDA to be submitted for the above-referenced drug product does not mean that the Agency has determined that an ANDA will be approved for the drug product. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the Agency.

To permit review of your ANDA submission, you must submit all information required under Sections 505(j)(2)(A) and (B) of the Act. To be approved, the drug product will, among other things, be required to meet current bioavailability requirements under Section 505(j)(2)(A)(iv) of the Act. We suggest that you contact the Director, Division of Bioequivalence, at (301) 827-5846 to determine the specific requirements for this drug product. During the review of your application, the Agency may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the one upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, HFA-305, Park Building, 12420 Parklawn Drive, Room 1-23, Rockville, MD 20857.

Sincerely yours,

Gordon R. Johnston for

Douglas L. Sporn
Director
Office of Generic Drugs